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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,624	04/12/2007	Akihiko Miyamoto	042269	1499
38834 7590 12/22/2011 WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036				
EXAMINER YOUNG, RACHEL T				
ART UNIT 3771		PAPER NUMBER		
NOTIFICATION DATE 12/22/2011		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentmail@whda.com

Office Action Summary**Application No.**

10/578,624

Applicant(s)

MIYAMOTO, AKIHIKO

Examiner

RACHEL YOUNG

Art Unit

3771

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-3 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-3 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/303)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____
- Paper No(s)/Mail Date ____

DETAILED ACTION

Amendment

1. This office action is responsive to the amendment filed on 12/2/11. As directed by the amendment: claims 1 and 2 have been amended, no claims have been canceled, and no new claims have been added. Thus, claims 1-3 are presently pending in the application.

Claim Objections

2. Claims 1-2 are objected to because of the following informalities: Claims 1 and 2 recite "plan view" and "side view" of the device, however these views can be interpreted in multiple ways with regards to a mouthpiece device. Although applicant refers to their own drawings using this language, there is no definition in the specification regarding these views. Also, in claims 1 and 2 "longitudinal direction" is recited, but it is unclear which view applicant is referring to with regards to the longitudinal direction of the device. Clarification is suggested.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinkade (5,062,422) in view of Steiner (2004/0182387), Foley (5,042,467) and MacRae et al. (2002/0046751).

Regarding claim 1, in fig. 7 Kinkade discloses a main unit 12 having a resilient material (Col. 2, ll. 12-13) tube (where 12 is pointing in fig. 1, tube passageway can be seen in fig. 8) used to aid an inhaler (Col. 1, ll. 10-13), and a junction 6 at a lower portion of the main unit; an engagement portion (where 10 is pointing in fig. 1) which is provided at an upper portion of the main unit, the junction having a horn-shape in plan view (view in fig. 7) such that a front joint piece and a rear joint piece of the junction project further in a longitudinal direction than left and right lateral ends of the junction (the front and rear portions do extend further than the longitudinal direction away from wings 3 than the left and right lateral ends of the junction), and having an arched shape in side view (when the device in fig. 7 is turned on its side (not fig. 8) an arch will be seen with the left and right lateral ends being at the top and the front and rear portions being at the bottom of the arch) such that the front joint piece and the rear joint piece correspond to bases of the arched shape and the left and right lateral ends correspond to a top of the arched shape; the engagement portion including and constituted of left and right projections, each having a holding member 2 at an end thereof. Kinkade is silent regarding a reed that produces a sound only when an inhalation has been correctly performed. However, Steiner teaches an inhaler with a reed located within the air-flow path that produces an audible signal when operating the inhaler correctly (proper airflow has been established, Page 4, para 60). Therefore, it would have been

obvious to one of ordinary skill in the art at the time the invention was made to modify Kinkade's inhaler with a reed, as taught by Steiner, for the purpose of assuring the patient of proper use and enhancing inhalation therapy. The modified Kinkade discloses a reed indicating that an inhalation has been correctly performed, but is silent regarding that the reed is located on the main unit and produces the sound when the inhaler aid is joined to the mouthpiece. However, Foley teaches a reed 90 located on a main unit 14 that produces a sound when connected with the mouthpiece. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Kinkade's main unit with the reed and noise production when the aid is connected to the mouthpiece, as taught by Foley, for the purpose of assuring the patient of proper use when the device is properly assembled and producing less interference with the medicament upon inhalation. The modified Kinkade is silent regarding that the reed is located on the right side of the main unit, however the specific location of the reed being on the right side of the main unit appears to be an obvious design consideration as it appears that the reed would perform equally as well located at any location on the circumference of the main unit. The modified Kinkade is silent regarding that the main unit is made from a silicon rubber. However, MacRae teaches an adapter body made from synthetic rubber, and preferably of a silicone material (Page 5, para 111). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kinkade's main unit with a silicone rubber material, as taught by MacRae, for the purpose of providing a flexible and comfortable mouthpiece.

Regarding claim 2, the modified Kinkade of claim 1 discloses the claimed invention, but is silent regarding a powder medicament. However, MacRae teaches a powder medicament (page 6, para 115). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Kinkade's main unit with a powder medicament, as taught by MacRae, for the purpose of providing different types of medication and therapies to a user.

Regarding claim 3, the modified Kinkade of claim 1 discloses the claimed invention.

Response to Arguments

5. Applicant's arguments with respect to claims 1-3 have been considered but are moot in view of the new grounds of rejection.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RACHEL YOUNG whose telephone number is (571)270-1481. The examiner can normally be reached on mon-fri 8 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/RACHEL T YOUNG/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771